K082797

OCT 17 2008



## 510(k) SUMMARY

### Blackstone Medical, Inc. Pedicle Screw System – 4.0 mm Diameter Screws

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| Sponsor: | Blackstone Medical, Inc.<br>1211 Hamburg Turnpike<br>Suite 300<br>Wayne, NJ 07470 |
| Registration Number: | 3004606875 |
| Contact Person: | Whitney G. Törning, Senior Director of Regulatory Affairs & Quality Assurance |
| Telephone Number: | 973.406.2838 |
| Fax Number: | 973.406.2938 |
| Email: | wtorning@blackstonemedical.com |
| Submitter: | Martin G. Sprunck<br>Regulatory Affairs Manager |
| Manufacturer: | Blackstone Medical, Inc.<br>90 Brookdale Drive<br>Springfield, MA 01104 |
| Registration Number: | 1225457 |
| Contract Manufacturer: | Pulse Technologies<br>2000 AM Drive<br>Quakertown, PA 18951 |
| System Name: | Blackstone Pedicle Screw System |
| Trade Name: | 4.0 mm Diameter Pedicle Screws |
| Common Name: | Posterior Thoracolumbar System |
| Product Code: | NKB – Orthosis, Spinal Pedicle Fixation, for Degenerative Disc Disease |
| Subsequent Product Codes: | MNI – Orthosis, Spinal Pedicle Fixation<br>MNH – Orthosis, Spondylolisthesis Spinal Fixation |

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| Regulatory Classifications: | Class III Preamendment Device, 888.3070 – *Pedicle Screw Spinal System* - *Class III Summary and Certification Required<br>Class II – 888.3070 – *Pedicle Screw Spinal System* |
| Review Panel: | Orthopedic Device Panel |
| Predicate Devices: | Blackstone Medical, Inc. Pedicle Screw System (K081684 SE 9/15/08)<br>Synthes Pangea Spine System (K052123 SE 9/23/05 & K052151 SE 12-7-05) |

**Intended Use / Indications for Use**

The Blackstone Pedicle Screw System is intended for posterior, non-cervical pedicle fixation. Pedicle screw fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for all of the following indications regardless of the intended use:

1) degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2) spondylolisthesis,
3) trauma (i.e., fracture or dislocation),
4) spinal stenosis,
5) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6) tumor,
7) pseudoarthrosis, and
8) failed previous fusion

The Blackstone Pedicle Screw System components are used with certain components of the Blackstone SFS system, including rods, rod connectors and cross-connectors.

**Technological Characteristics**

The Blackstone Pedicle Screw System 4.0 mm Diameter Screws consists of an assortment of multiaxial and monoaxial pedicle screws.

**Performance Data**

Mechanical testing of the Blackstone Pedicle Screw System 4.0 mm Diameter Screws was conducted which demonstrates that the system is substantially equivalent to predicate devices that have the same intended use, similar indications, technological characteristics and principles of operation.

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**Basis of Substantial Equivalence**

Mechanical testing was conducted to demonstrate that the additional 4.0 mm diameter screw components are substantially equivalent to the current Blackstone Pedicle Screw System, (K081684 SE 9/15/08), which has been cleared by FDA for the purpose of building a spinal implant construct in the non-cervical spine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Blackstone Medical, Inc.
% Ms. Whitney G. Törning
Senior Director of Regulatory Affairs
& Quality Assurance
1211 Hamburg Turnpike, Suite 300
Wayne, New Jersey 07470

OCT 17 2008

Re: K082797
Trade/Device Name: Blackstone Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Names: Pedicle screw spinal system.
Regulatory Class: III
Product Code: NKB, MNI, MNH
Dated: September 22, 2008
Received: September 23, 2008

Dear Ms. Törning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K082797

System Name: Blackstone Pedicle Screw System
Device Name: 4.0 mm Diameter Pedicle Screws

Indications for Use:

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8) failed previous fusion

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Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K082797